UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CONEY ISLAND PREP; LESLIE-BERNARD JOSEPH; HOUSING WORKS, INC.; CHARLES KING; MARK LEVINE; and ALEXANDRA GREENBERG,	:	
Plaintiffs,	:	**COMPLAINT**
-against-	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; DR. ROBERT KADLEC, *in his official capacity as Assistant Secretary of Health and Human Services*; CENTERS FOR DISEASE CONTROL AND PREVENTION; DR. ROBERT R. REDFIELD, *in his official capacity as Director for the Centers for Disease Control and Prevention*,	:	
Defendants.	:	

INTRODUCTION

1. Coney Island Prep ("CIP"), a public charter school in Brooklyn, NY; Housing Works, Inc. ("Housing Works"), a New York City non-profit health and housing organization; Leslie-Bernard Joseph; Charles King; Mark Levine; and Alexandra Greenberg (collectively, "Plaintiffs"), on personal knowledge as to their own actions and information and belief as to the actions of others, bring this action to compel the above-captioned Defendants ("Defendants" or "Federal Agencies") to fulfill duties that they have unlawfully failed to perform during the ongoing public health emergency presented by the 2019 novel coronavirus ("SARS-COV-19" or "Covid-19") pandemic. While the focus of this lawsuit is Defendants' violations of the Administrative Procedure Act by the illegal conduct complained of herein and more specifically described below, this Court cannot ignore that Defendants' misdeeds are part of a pattern of misconduct and neglect

in response to a pandemic that has cost hundreds of thousands of lives in this country and has inflicted pain, suffering and illness upon millions more. The irreparable injury is clear.

2. As of this morning, over nine million Americans have been infected by Covid-19, the disease caused by the coronavirus SARS-CoV-2, and over 229,000 of them have died. The toll has been especially acute within Black and Latinx communities, with Black and Latinx persons three times as likely to become infected and twice as likely to die from Covid-19. America has less than one-twentieth of the world's population but roughly one-fifth of the world's infections and deaths.

3. Covid-19's devastating impact on America was not inevitable, and, in fact, was foreseen by the federal government. Last year, with broad, bipartisan support, the United States Congress passed, and the President signed, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019) (the "Pandemic Preparedness Act" or "Act"). The Act mandates the creation of a "biosurveillance network" to provide "near real-time" information on the progress of public health emergencies like the Covid-19 pandemic, 42 U.S.C. § 247d-4(c), (j), and prescribes numerous pandemic response measures. In sum, Congress designated the Federal government to be the very body that coordinates the data-collection and reporting necessary so that Congress, local governments, the public and Plaintiffs can mitigate public health risks effectively and efficiently.

4. But now that the time has come, the Federal government is failing to do so. Instead, Defendants react to the pandemic by shifting their responsibilities to local governments and private entities, refusing to empower the public with information and access it needs, and shutting their doors to experienced input that would produce a more resilient response. In so doing, Defendants unlawfully withhold and unreasonably delay the numerous duties mandated by Congress—duties

that are always present, but are expanded and amplified during a public health emergency. The law is clear, however, these duties are mandatory: the Plaintiffs and the public are entitled to the information and participation that Congress granted to them and that Defendants are unlawfully withholding.

5. Defendants' failures fall into three basic categories: first, failing to carry out biosurveillance duties; second, failing to fulfill reporting obligations (including the data collection required to prepare required reports); and third, declining to allow the public to participate in formulating policy responses, all as required by statute. These obligations are subject to specific deadlines that Defendants have not met.

6. *First*, Defendants fail to fulfill Congress' express biosurveillance mandate (collectively hereinafter, "Withheld Biosurveillance Duties"). The statutory deadlines have passed for: (1) the publication of "technical and reporting standards" for federal, state, local and tribal health agencies to ensure "timely sharing" of "essential information" and "coordination" to maximize preparedness and response," 42 U.S.C. § 247d-4(b)(2)-(3); (2) the provision of formal notice and an opportunity for the public to comment, under 5 U.S.C. § 533, as to the "technical and reporting standards"; (3) the completion of a Biological Threat Detection Report that must include a "description of the capabilities of detection systems in use by Federal departments and agencies" to rapidly detect the presence of biological threats," P.L. 116-22 § 205, 133 Stat. 905, 924–25; and (4) the convening of a public meeting "for purposes of discussing and providing input on the potential goals, functions, and uses of the [biosurveillance] network," 42 U.S.C. § 247d-4(c)(5)(B). Because of these failures, Defendants will not be able to fulfill their duty to prepare a Strategy and Implementation Plan for biosurveillance ("Biosurveillance SIP"), by the statutory deadline of December 24, 2020, "that identifies and demonstrates the measurable steps the

Secretary will carry out to develop, implement, and evaluate the [biosurveillance] network" and includes deadlines by which Congress and the public can hold the agency accountable, 42 U.S.C. § 247d-4(c)(6).

7. *Second*, Defendants fail to fulfill reporting and disclosure duties relevant to the Covid-19 pandemic (collectively hereinafter "Withheld Reporting Duties"). These include the failure to complete and/or disseminate: (1) four annual reports on national health resources and statistics, 42 U.S.C.§ 242m(a)(1)-(2); (2) a national disease prevention data profile, *id.* § 242p; (3) reports from state and local agencies receiving federal funding for public health security and surge capacity, *id.* §§ 247d-3a(i)-(j), 247d-3b(i); (4) a Strategy and Implementation Plan regarding medical countermeasure preparations ("Countermeasures SIP"), *id*. § 300hh-10(d); (5) a five-year budget based on the priorities in the Countermeasures SIP, *id.* § 300hh-10(b)(7); (6) a report regarding biological agents and toxins and their countermeasures, 42 U.S.C. § 262a(k); (7) a report on international cooperation in the research and development of vaccines and other qualified pandemic or epidemic countermeasures, Pandemic Preparedness Act § 606, 133 Stat. 905, 959; (8) a report containing recommendations as to maintaining an adequate national blood supply for emergency response, *id.* § 209, 133 Stat. 905, 929; (9) the annual Threat Based Review of the Strategic National Stockpile ("SNS") of countermeasures for use in the event of a public health emergency, *id.* § 247d-6b(a)(2); (10) annual material threat determinations and related assessments as to the SNS stockpile's readiness, *id*. § 247d-6b(c)(2)-(3); (11) a National Healthcare Quality and Disparities Report on healthcare disparities by race and ethnicity, *id*. § 299a-1(a)(6); (12) a biennial report from the Office of Minority Health, *id*. § 300u-6(f).

8. *Third*, the statutes expressly require that the public participate in formulating some of the policy responses, but Defendants are denying the public these opportunities (collectively

hereinafter "Withheld Participation Duties"). Defendants fail to: (1) solicit the formal input of experts and stakeholders in the preparation of the Countermeasures SIP, 42 U.S.C. § 300hh-10(d)(2)(H); and (2) convene a meeting to discuss genomic engineering technologies, health security, and related countermeasures important to combatting infectious diseases, to include "representatives from academic, private, and nonprofit entities . . . and other stakeholders," Pandemic Preparedness Act § 605, 133 Stat. 905, 958-59, after which Defendants must prepare a report. Plaintiffs are among those specifically intended to participate in and/or benefit from these deliberations and reports.

9. Defendants' multiple failures to fulfill their statutory obligations affect every single American in some form. They also particularly, and concretely, impact Plaintiffs. All Plaintiffs have clear interests, play important roles in New York City's response to the pandemic, and suffer directly from the Federal government's failures. Moreover, all Plaintiffs serve predominantly Black and Latinx communities who have been hardest hit by the direct and collateral costs of this pandemic. With the fall and winter threatening a second wave, the City will be hard hit again by infections and deaths, and all Plaintiffs will be on the frontlines of the City's response in its schools, in its streets, in its policy community, and in its hospitals.

10. Plaintiff CIP, for example, serves neighborhoods that were among the hardest hit during New York's difficult first wave. CIP, acting *in loco parentis*, is charged with ensuring the health and safety of its students. Defendants' failures cause it to divert significant resources from its core educational mission to addressing Covid-19, and these injuries are compounded by human costs to CIP's students, their family members, and staff who have been infected, suffered serious bodily harm, and/or lost loved ones. Plaintiff Housing Works, led by Plaintiff Charles King, is a community health organization on the frontlines of the pandemic, operating testing facilities and

isolation and quarantine housing that serve homeless and at-risk persons suffering with HIV/AIDS and other chronic conditions, for whom exposure to Covid-19 can have outsized consequences. Plaintiff Mark Levine, a New York City Councilmember, is Chair of the City Council's Committee on Health and oversees legislative efforts to respond to the pandemic. Plaintiff Alexandra Greenberg is a medical student and public health advocate whose work relates to infectious diseases and frontline care. Plaintiffs Levine and Greenberg are forced to close the research gaps left by Defendants' abdication of their legal duties and divert their attention from other urgent public health concerns.

11. Defendants' failures cause Plaintiffs irreparable harm, and that harm grows with each passing day. The information and participatory rights injured by Defendants' inaction fall squarely within the zone of Plaintiff's interests. Absent accurate information on the spread of the virus among the communities they serve, Plaintiffs will continue to bear the organizational and individual burdens of the Federal government's failures for the remainder of the pandemic.

12. Plaintiffs seek declaratory and injunctive relief from the Court to: (1) compel Defendants to perform the Withheld Biosurveillance Duties, expressly intended to respond to public health emergencies like the Covid-19 pandemic and whose deadlines have lapsed; (2) compel Defendants to perform the Withheld Reporting Duties and Withheld Participation Duties, also relevant to responding to Covid-19; (3) compel Defendants to perform sufficient public health surveillance to meet their future reporting obligations and other statutory mandates; (4) compel Defendants to undertake the required data collection and reporting; (5) impose a scheduling order with mandatory deadlines for the completion of these duties; and (6) retain jurisdiction and place such relief under Court supervision or receivership to ensure the government's timely and

complete execution of the above; and (7) award such other relief as necessary and appropriate to carry out the statutory mandates and purposes.

13. This is a case about the Federal government's failure to discharge its legally required duties at a time the country needs them most. But it is not too late to act. Relief from this Court can ensure that the further response to the Covid-19 pandemic is in line with statutory requirements and minimizes needless suffering.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this case arises under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA"). This Court has remedial authority pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, the Mandamus Act, 28 U.S.C. § 1361, and the All Writs Act, 28 U.S.C. § 1651(a).

15. Venue properly lies in the Southern District of New York because several plaintiffs reside in the District, 28 U.S.C. § 1391(e)(1), and because a substantial part of the events or omissions giving rise to this action occurred in the District. 28 U.S.C. § 1391(b).

PARTIES

16. Plaintiff CIP is a public charter school in Brooklyn, New York. Founded in 2008 with an initial class of fifth graders, the school has grown to serve children from Kindergarten through 12th grade. It serves a diverse community of students and families from the Coney Island area and is committed to preparing every student to succeed in the college or career of their choice.

17. Plaintiff Leslie-Bernard Joseph is a resident of Brooklyn, New York and the Chief Executive Officer of CIP, having previously served as the school's Dean of Students and Deputy Executive Director or as a member of its Board of Directors since its founding. He has led the organization through the difficult challenges presented by the Covid-19 pandemic, and the school's efforts have been held up as an example of responsible pandemic preparedness and response. The

education of CIP students and the health and livelihood of their families have been severely impacted by the Covid-19 pandemic and Defendants' failed duties.

18. Plaintiff Housing Works is a New York City non-profit addressing homelessness, HIV/AIDS, and other chronic health conditions. Housing Works operates health clinics, supportive housing centers, career training programs, legal services, as well as profitable thrift stores, a bookshop and a café. It publicly advocates on a wide range of health and homelessness issues in New York City, Albany, Washington, D.C., Puerto Rico and Haiti. In response to the Covid-19 pandemic, Housing Works has partnered with City agencies to offer free Covid-19 testing and to operate housing centers to isolate and quarantine infected or exposed persons.

19. Plaintiff Charles King is a resident of Manhattan, New York and the CEO and a founder of Housing Works. A public voice on health and housing issues, he has led the organization's response to Covid-19 pandemic, innovated a number of new programs to address the pandemic's health and housing impacts, and partnered with the City to offer testing, treatment and housing services to the public.

20. Plaintiff Mark Levine is a resident of Washington Heights, Manhattan, New York and the New York City Councilmember representing the 7th District in Northern Manhattan. He serves as the Chair of the Council Committee on Health, and is a leader on many issues including housing, education, and economic justice, as well as the City's response to the Covid-19 pandemic.

21. Plaintiff Alexandra Greenberg is a resident of Manhattan, New York and a medical student at SUNY Downstate College of Medicine. She is a public health researcher and advocate who throughout the Covid-19 pandemic has been advocating with others in the Right to Health Action movement for comprehensive and equitable health interventions.

22. Defendant Department of Health and Human Services ("HHS") is a federal agency responsible for the nation's health policy and programs, including "all health statistical and epidemiological activities" related to the Covid-19 pandemic and the nation's public health. *See* 42 U.S.C. § 242b. HHS is a Department of the Executive Branch of the United States Government and is an agency within the meaning of the APA. 5 U.S.C. § 551(1).

23. Defendant Alex. M. Azar II ("Azar" or the "Secretary") is the Secretary of HHS and a member of the White House Coronavirus Task Force. He is sued in his official capacity.

24. Defendant Dr. Robert Kadlec is the Assistant Secretary for Preparedness and Response at HHS and a member of the White House Coronavirus Task Force. He is sued in his official capacity.

25. Defendant Centers for Disease Control and Prevention ("CDC") is responsible for the prevention and control of diseases and other preventable conditions and for responding to public health emergencies like the Covid-19 pandemic. CDC is an operating division of HHS and is an agency within the meaning of the APA. 5 U.S.C. § 551(1).

26. Defendant Dr. Robert R. Redfield is the Director of the CDC, the Administrator of the Agency for Toxic Substances and Disease Registry, and a member of the White House Coronavirus Task Force. He is sued in his official capacity

STATEMENT OF FACTS

I. STATUTORY BACKGROUND

A. Congress has charged HHS and its agencies with the duty to collect, analyze and disseminate comprehensive data regarding the nation's public health.

27. The Public Health Service Act ("PHSA"), 42 U.S.C. § 201 *et seq.*, primarily directs HHS and its agencies, like the CDC, to, *inter alia*, collect and disseminate data related to public health to ensure that public health policy can be accurately targeted and scaled to each unique

challenge. To this end, the Secretary is directed to "coordinate . . . all health statistical and epidemiological activities," 42 U.S.C. § 242b, such as the testing and tracing necessary to understand the scope of public health emergencies like the present pandemic.

28. HHS has a general duty not just to collect adequate data but to publicly disseminate this data in the form of "high quality, timely, and comprehensive" disclosures on "as wide a basis as is practicable." 42 U.S.C. § 242m.

B. Recognizing the role of HHS in collecting and disseminating critical public health information, Congress enacted legislation in 2019 to improve federal coordination of the nation's preparations for and response to pandemics and other public health emergencies.

29. On June 24, 2019, anticipating the risks posed by global pandemics like Covid-19, Congress passed the Pandemic Preparedness Act, which was intended to "reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response." P.L 116-22, 133 Stat. 905 (2019). The law passed out of committee by unanimous consent, passed the House and Senate by voice vote on June 24, 2019, and was signed by the President on the same day.

30. In a press release, Defendant Kadlec recognized that the Act was intended to "ensur[e] that our nation is ready and able to withstand the adverse health effects of public health emergencies and disasters, whether a severe storm, *a disease pandemic*, or a bioterror attack" and that certain emergencies "can be so catastrophic that *direct federal support is needed*, and with this law, communities can continue to count on . . . medical professionals, services and equipment from across the country to provide medical care in support of hospitals, shelters, and whole communities after a disaster." Robert Kadlec, *New Law Strengthens U.S. Efforts to Prepare, Respond and Recover from Disasters*, U.S. Dept. of Health & Human Servs. (Jun. 25, 2019) (emphasis added).

31. The Act established new mechanisms to prepare for and respond to public health emergencies (including pandemics), new standards for research and data collection, and new reporting requirements. It specifically sought to improve the CDC's "capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks." 42 U.S.C. § 247d-4(a)(3)(c).

32. To this end, the Act charged the HHS Secretary with developing a "biosurveillance network": "a *near real-time* electronic nationwide public health situational awareness capability through *an interoperable network* of systems to share data and information to enhance early detection of, rapid response to, and management of, potentially *catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies* that originate domestically or abroad." 42 U.S.C. § 247d-4(c)(1) (emphasis added). The network contemplated by Congress requires federal coordination of the contributions from governmental and private health entities to collect and disseminate "data and information transmitted in a standardized format from": "[s]tate, local, and tribal public health entities, including public health laboratories"; "[f]ederal health agencies"; "zoonotic disease monitoring systems"; and various kinds of "public and private sector public health"; and "environmental health" organizations. 42 U.S.C. § 247d-4(c)(3)(A)

33. The Pandemic Preparedness Act emphasizes the need for the federal government to solicit and consider input from experts and the wider public. The Act calls for some form of "report[ing]," "notif[ication]," "oversight" or "transparency" over 80 times in the legislative text. P.L 116-22, 133 Stat. 905. Similarly, it calls for some form of "input," "expert[ise]," or "advi[ce]" over ninety times. *Id.* The prevalence of this language in the new law emphasizes the importance of transparency, oversight and public debate in the development and execution of the nation's public health laws, and it echoes the broad mandate enshrined in the public health statutory scheme

that Defendants must provide the public with "high quality, timely, and comprehensive" information on "as wide a basis as is practicable." 42 U.S.C. § 242m.

C. The biosurveillance network mandated by the Pandemic Preparedness Act requires Defendants' coordinate, among other things, testing and contact tracing in order to provide "near real-time" information regarding the progress of the Covid-19 pandemic.

34. The Pandemic Preparedness Act defines "biosurveillance" as "the process of gathering *near real-time* biological data . . . in order to achieve early warning and identification of such health threats, *early detection* and *prompt ongoing tracking* of health events, and overall situational awareness of disease activity." 42 U.S.C. § 247d-4(j) (emphasis added).

35. As recently as January 2019, in a report titled "Public Health Emergency Preparedness and Response Capabilities," the CDC defined "Biosurveillance" as (1) "Public Health Laboratory Testing"; and (2) "Public Health Surveillance and Epidemiological Investigation." Ctrs. for Disease Control and Preparedness, *Public Health Emergency Preparedness and Response Capabilities* (Jan. 2019).

36. The law already charges HHS and CDC with a number of other epidemiological and health surveillance obligations in addition to the Withheld Biosurveillance Duties. *See* 42 U.S.C. §300hh–13 (requiring improvements of health surveillance technology); 42 U.S.C. §300hh–14 (requiring health surveillance during natural disasters); and 42 U.S.C. §300hh–16 (ensuring that the biosurveillance network seeks data to safeguard "at risk" populations); 42 U.S.C. §300hh–31 (directing epidemiology and lab testing grants). Public health emergency laws make clear that testing and biosurveillance are essential parts of HHS' emergency response. *See* 42 USC § 247d-6b(a)(1) (requiring "diagnostic tests" be held in the strategic national stockpile) and 42 USC § 247d(b)(2)(D) (dedicating emergency funding to "strengthen biosurveillance capabilities and laboratory capacity").

D. In order to ensure the creation of a national biosurveillance network, the Pandemic Preparedness Act included explicit deliverables and deadlines that have not been met and/or will not be met without intervention by this Court.

37. The Pandemic Preparedness Act is not merely advisory; it created numerous obligations that HHS and other agencies were required to meet in order to ensure that the United States could mount an effective response to a pandemic.

38. In particular, it detailed a clear roadmap for the implementation of the biosurveillance network with an explicit set of "*required* activities" to effectuate a "joint public and private sector process" to implement "interoperability standards," "define minimal data elements," "build upon existing State, local, and tribal capabilities," "develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network," and "pilot test standards and implementation specifications." 42 U.S.C. § 247d-4(c)(5)(A) (emphasis added).

39. Defendants' Withheld Biosurveillance Duties include:

(a) By **December 21, 2019**, the Secretary was required to convene a *public meeting* "for purposes of discussing and providing input on the potential goals, functions, and uses of the network" and to include representatives from federal, state, local and tribal health agencies; public and private sector expertise; and other such stakeholders. P.L. 116-22 § 205(d), 133 Stat. 905, 920 (codified at 42 U.S.C. § 247d-4(c)(5)(B)). Secretary Azar has never done this.

(b) Also by **December 21, 2019**, the Secretary was required to submit a "Biological Threat Detection Report" to various committees in the House of Representatives and Senate "on the state of Federal biological threat detection efforts." *Id.* § 205(c), 133 Stat. at 924–25. The Report must describe the "detection systems in use by Federal departments and agencies" and the efforts to "collaborate with *State, local, Tribal, and territorial* public health laboratories and other users of biological threat detection systems." *Id.* (emphasis added). Secretary Azar has never done this.

(c) And by **June 24, 2020**, the Secretary was required to "adopt technical and reporting standards, including standards for [data] interoperability" to be designed "in cooperation with health care providers, State, local, Tribal, and territorial public health officials, and relevant Federal agencies." *Id.* § 205(a), 133 Stat. at 918-19 (amending 42 U.S.C. § 247d-4(b)(3)). These detailed standards are to be "made available *on the internet*

website of the Department of Health and Human Services, in a manner that does not compromise national security." *Id.* (emphasis added). Secretary Azar has never done this.

(d) Moreover, once these "technical and reporting standards" are promulgated, the Secretary is required to offer formal notice and an opportunity for the public to comment on the rulemaking pursuant to the Administrative Procedure Act, 5 U.S.C. § 553. Secretary Azar has never done this.

40. Finally, by **December 24, 2020**, the Secretary is required to submit the Biosurveillance SIP to the "congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan" that is "informed by the public meeting" described above and "that identifies and demonstrates the measurable steps the Secretary will carry out to develop, implement, and evaluate the [biosurveillance] network," including deadlines by which Congressional mandates would be met. P.L. 116-22 § 205(a), 133 Stat. at 921 (codified at 42 U.S.C. § 247d-4(c)(6)). Since Secretary Azar has not held the statutorily mandated public meeting, it is unlikely that he will comply with this requirement.

41. In sum, Defendant Azar has accomplished *none* of these required steps mandated by the Act. He has not held the "public meeting" that Plaintiffs would have participated in, contributed to, or otherwise used to inform their efforts to fight Covid-19. He has not submitted the Biological Threat Detection Report to Congress that would offer vantage on Plaintiffs' capacity to diagnose and track the progress of this virus. He also has not made publicly available the "technical and reporting standards" that HHS would use to build the government's surveillance and biosurveillance capacities, upon which Plaintiffs are entitled to comment.

42. Given these failures, Defendant Azar will not meet his upcoming obligation to submit the Biosurveillance SIP, resulting in further derogation of duty.

E. Beyond the biosurveillance network, the Pandemic Preparedness Act and other federal public health laws mandate further reports and deliverables, the deadlines for which have not been met and/or will not be met without intervention by this Court.

43. Beyond Defendants' obligation to fulfill their Withheld Biosurveillance Duties, the Pandemic Preparedness Act requires Defendants to publish a number of reports and make other disclosures intended to arm the public with information with respect to Covid-19, the government's preparedness and response to public health emergencies, and the public health context in which this emergency and interventions to combat it arise.

44. Defendants' Withheld Reporting Duties under the Pandemic Preparedness Act require several disclosures directly to the public, the deadlines for which have already lapsed:

(a) The Secretary is required to compile and publish **on the internet in a "timely manner"** the **annual** reports submitted by states and localities that have received federal emergency preparedness funding. 42 U.S.C. §§ 247d-3a(j), 247d-3b(i). These reports are in part purposed to "properly evaluate and compare the performance of different entities" and to provide transparency into which interventions have been most beneficial. *Id.* § 247d-3a(i)(1). To date, Secretary Azar has published no such annual reports.

(b) Defendant Kadlec, in conjunction with the Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE"), is required to "develop and submit" to Congress and make "*publicly available*" a Countermeasures SIP that identifies threats, assesses the present supply of medical countermeasures, and outlines the steps necessary for countermeasures preparations to meet their legal requirements **by March 15, 2020** and biennially thereafter. 42 U.S.C.A. § 300hh-10(d)(1) (emphasis added); P.L. 116-22 § 402(b), 133 Stat. at 943 (amending 42 U.S.C. § 300hh-10(d)). Prior to the statute's amendment by the Pandemic Preparedness Act, the Assistant Secretary was required to produce the Countermeasures SIP **annually**. *See* 42 U.S.C.A. § 300hh-10(d)(1) (effective Dec. 13, 2016, to June 13, 2019). On information and belief, the Assistant Secretary has not submitted any Countermeasures SIP to Congress since **2017**. The last publicly available Countermeasures SIP is dated **December 2017**, indicating that the PHEMCE SIPs for the years **2018, 2019, and 2020** are all withheld.

(c) Relatedly, Defendant Kadlec must prepare **by March 15 each year** a five-year budget plan based on the medical countermeasure priorities, including "such agents that are novel or emerging infectious diseases," set in the SIP. *Id.* § 501, 133 Stat. at 950 (amending 42 U.S.C. § 300hh-10(b)(7)). This document must be submitted to relevant congressional committees and made publicly available by the deadline. 42 U.S.C. § 300hh-10(b)(7)(E). To date, no public version has been made available on the PHEMCE website since **2018**.

45. Defendants' Withheld Reporting Duties also arise under other public health laws and require several disclosures directly to the public that have already gone unperformed:

(a) With respect to the SNS and the readiness of federal medical countermeasures, the Secretary is obligated to make certain information publicly available so as to improve the transparency of the agency's emergency readiness and the degree to which the nation is appropriately prepared for public health threats. Accordingly, the Secretary must submit to Congress "**on an annual basis** all current material threat determinations," 42 U.S.C. § 247d-6b(c)(2)(C), and to "institute a process for *making publicly available* the results of [such] assessments," as to material threats and the sufficiency of stockpiled countermeasures, *see* 42 U.S.C. § 247d-6b(c)(3)(A)-(B) (emphasis added). The Secretary has not done this.

(b) The Secretary must accomplish a number of these Duties through the National Center for Health Statistics ("NCHS"), an HHS entity that in part coordinates health statistics collection and reporting across the Department. *See* 42 U.S.C. § 242m (generally). The Secretary, through the NCHS, is required to coordinate among federal agencies and state, local, tribal and territorial agencies. *See, e.g.*, 42 U.S.C. § 242m(f) (mandating "Federal-State Cooperation"), *id.* § 242m(f) (instituting a Cooperative Health Statistics Service across federal, state, local agencies). Through the NCHS, the Secretary must coordinate data collection programs across the HHS, and the NCHS routinely collaborates with other entities in their reports and public disclosures. As a result, through NCHS, the Secretary must ensure across HHS such programs are "high quality, *timely*, comprehensive as well as specific, standardized, and adequately analyzed and indexed," and he "*shall* publish, make available, and disseminate such statistics on as wide a basis as is practicable." 42 U.S.C. § 242m(c) (emphasis added):

(i) The Secretary, through the NCHS, is obligated to publish four reports **by March 15 of each year**: regarding (1) national health care costs and financing, (2) national health resources, (3) the utilization of health resources, and (4) the health of the nation's people. 42 U.S.C. § 242m(a)(1)-(2). The Secretary is required to submit these reports to the President and Congress and to "disseminate such statistics on as *wide a basis* as is practicable." 42 U.S.C. § 242m(c) (emphasis added). The Secretary has not done this.

(ii) The Secretary, through the NCHS, is also required to prepare "a national disease prevention data profile . . . *to increase public awareness* of the prevalence, incidence, and any trends in the preventable causes of death and disability in the United States." 42 U.S.C. § 242p(a) (emphasis added). Such a report must include certain data relevant to Covid-19 adverse outcomes, such as on "mortality and morbidity." *Id.* § 242p(a)(1-4). This report is due to Congress every third year, the last deadline falling **on March 15, 2020**. *Id.* The Secretary has submitted no such report to Congress or made one publicly available.

46. Defendants' Withheld Reporting Duties include reports specifically addressing the nation's health disparities, including those by race and ethnicity, and proposals for their mitigation; these reports have gone unperformed for a number of years:

(a) The Secretary must accomplish other of these Duties through an HHS agency called the Agency for Healthcare Research and Quality ("AHRQ"). In addition to its broader mandate, the AHRQ is charged with identifying "causes of and barriers to reducing [] health disparities" including "socioeconomic status, attitudes toward health, the language spoken, the extent of formal education, the area or community in which the population resides, and other factors," 42 U.S.C. § 299a-1(a)(2), and must research health care "in inner-city areas, and in rural areas," as well as among "low income groups, minority groups, women, children, the elderly," and individuals with chronic conditions or disabilities. 42 U.S.C. § 299(c). Accordingly, the Secretary, acting through the AHRQ, is required **annually** to submit to Congress a "National Healthcare Quality and Disparities Report," "regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations." 42 U.S.C. § 299a-1(a)(6). Though this report has been made publicly available since 2003, *id.*, the Secretary has not submitted this report to Congress nor made it available to the public **since 2018**.

(b) The Secretary must accomplish other of these Duties through the Office of Minority Health ("OMH"), an HHS agency charged with "improving minority health and the quality of health care minorities receive and eliminating racial and ethnic disparities." 42 U.S.C. § 300u-6(a). The Secretary, through the OMH, must submit **biennial reports** to Congress "evaluating the extent to which [OMH] activities have been effective in improving the health of racial and ethnic minority groups." *Id*. § 300u-6(f). Versions of this report have been made available online. The Secretary has not submitted this report to Congress or made one publicly available **since 2015**.

47. Defendants' Withheld Reporting Duties under the Pandemic Preparedness Act and other public health laws also require other deliverables to Congress, the deadlines for which have already lapsed:

(a) The Secretary must perform an annual Threat-Based Review with respect to the sufficiency of the SNS contents—the first two reviews were **due June 15, 2019** and **March 15, 2020**, 42 U.S.C. § 247d-6b(a)(2)—and Congress received neither year's report; the provisions for the Threat-Based Review make clear that their contents of these reports are materially similar to the Countermeasures SIP and the SNS annual material threat assessments, both of which Defendants by law must make available to the public, *see id.* (citing 42 U.S.C.A. § 300hh-10) and 42 U.S.C. § 247d-6b(c)(2)(A), (c)(3)(A)-(B);

(b) **By June 24, 2020**, a report on the implementation of recommendations from the Federal Experts Security Advisory Panel ("FESAP") regarding the regulation of highly dangerous biological agents and toxins and their countermeasures, *id.* § 405, 133 Stat. at 949 (amending 42 U.S.C. § 262a(k))—previous FESAP reports and related implementation plans have been routinely published since 2010;

(c) **By June 24, 2020**, a report on US-international coordination during recent public health emergencies on the research and development of qualified pandemic or

epidemic countermeasures, including vaccines, *id.* § 606, 133 Stat. at 959, newly required by the Pandemic Preparedness Act;

(d) And **by June 24, 2020**, a report containing recommendations related to maintaining an adequate national blood supply, intended to "to promote safety and innovation," *id.* § 209, 133 Stat. at 929, also newly required by the Pandemic Preparedness Act;

48. Each of Defendant's Withheld Reporting Duties represent important contributions to the country's knowledge and capacity to combat the Covid-19 pandemic. Such deliverables therefore must be made public as part of HHS' general duties to make the data it collects available to the public in the form of "high quality, timely, and comprehensive" disclosures on "as wide a basis as possible," 42 U.S.C. § 242m, and pursuant to the agency's duty under the Administrative Procedure Act to "make available to the public [such] information," 5 U.S.C. § 552. Such disclosures are also consistent with the legislative purpose of the Pandemic Preparedness Act, taken as a whole, to improve transparency, oversight and public participation in the development and execution of our public health system. As far as Plaintiffs are aware, none of these obligations have been met by their respective deadlines, and there is no evidence of these submissions in the Federal Register.

F. The Pandemic Preparedness Act also mandates the federal government provide opportunities for public participation in the regulatory and/or rulemaking process, the deadlines for which have not been met and/or will not be met without intervention by this Court.

49. Per Defendants' Withheld Participation Duties, the Pandemic Preparedness Act requires Defendants to engage members of the public in the regulatory and rulemaking processes and provide opportunities for stakeholders to inform the process with their experience and expertise:

(a) Defendant Kadlec must "incorporate input from Federal, State, local, and tribal stakeholders," in preparing the Countermeasures SIP that was due **by March 15, 2020**. 42 U.S.C. § 300hh-10(d)(2)(H). There is no evidence that Defendant Kadlec or the PHEMCE has sought input from State, local or tribal stakeholders.

(b) **By June 24, 2020**, the Secretary must convene a meeting "to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security." P.L. 116-22 § 605, 133 Stat. 905, 958-59. Relevant to Covid-19 preparedness and response is the role genomic engineering plays in "medical countermeasure development" for infectious diseases and other biological threats, and similar topics. *Id.* The Secretary must include "representatives from academic, private, and nonprofit entities"—those with expertise in genome engineering, but also those with non-genomic "medical" expertise—as well as "other relevant stakeholders." *Id.* By March 18, 2021, Defendant Kadlec must prepare a report on the discussion and submit it to the relevant committees in Congress. *Id.* The Secretary has not convened the meeting or submitted the report.

50. Defendants' Withheld Participation Duties, together with their Withheld Biosurveillance and Withheld Reporting Duties, together constitute a dereliction of duty with respect to Defendants' public health responsibilities during the Covid-19 public health emergency—failures which directly harm Plaintiffs' informational and procedural rights.

II. FACTUAL BACKGROUND

A. Despite ample notice, Defendants did not adequately prepare for or respond to the threat of a pandemic, and they now ignore and attack their obligations to inform the public and perform biosurveillance to contain the coronavirus.

51. Mere months after the Pandemic Preparedness Act was passed, it was reported that the federal government learned of an outbreak of a novel coronavirus in Wuhan, China. *See* Zachary Cohen *et al*, *US Intelligence Agencies Started Tracking Coronavirus Outbreak in China as Early as November*, CNN (Apr. 9, 2020).

52. By January 2020, Defendants understood that the virus presented a unique global pandemic threat, as evidenced by intelligence agency reports, the HHS, and White House advisors—as well as other official public statements. *See* Greg Miller, *President's intelligence briefing book repeatedly cited virus threat*, WASH. POST (Apr. 27, 2020); Hearing on an Emerging Disease Threat: How the U.S. is Responding to Covid-19, the Novel Coronavirus, 116th Cong. 1-4 (2020); Maggie Haberman, *Trade Adviser Warned White House in January of Risks of a Pandemic*, N.Y. TIMES (Apr. 6, 2020).

53. On January 31, 2020, the Secretary declared a public health emergency. *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus*, HHS.GOV (Jan. 31, 2020). Despite that declaration, he testified before a Congressional committee weeks later that the risk to the public remained "low," and that the coronavirus would "look and feel to the American people more like a severe flu season in terms of the interventions and approaches you will *see*." *House Committee on Ways & Means Testimony*, C-SPAN (Feb. 27, 2020).

54. Privately, however, Defendants were privy to alarming information about how contagious and lethal Covid-19 was. Official emails indicate that, as early as February 23, Defendant Kadlec was aware that Covid-19 could be spread asymptomatically, that seemingly healthy individuals were putting others at serious risk, and that federal surveillance efforts were insufficient. *See* Eric Lipton, *He Could Have Seen What Was Coming: Behind Trump's Failure on the Virus*, N.Y. TIMES (Apr. 11, 2020). Kadlec conceded that, this being true, "we have a huge hole on our screening and quarantine effort." *Id.*

55. Confronted with a real pandemic, Defendants chose not to set in motion the tasks delineated in the Pandemic Preparedness Act (or elsewhere in the PHSA), and, instead, "turn[ed] a blind-eye" to the pandemic in an effort to deflect bad news ahead of the November 2020 national election. Zachary Cohen *et al.*, *Bolton says Trump Turned 'a Blind Eye' to the Coronavirus Pandemic*, CNN (June 24, 2020). Dr. Rick Bright, the former head of the Biomedical Advanced Research and Development Authority ("BARDA"), the office within HHS responsible for the development medical countermeasures, filed a whistleblower complaint, alleging that "in this Administration, the work of scientists is ignored or denigrated to meet political goals and to advance President Trump's re-election aspirations" and defending "non-politicized, un-manipulated public health guidance from career scientists with the expertise to prepare a plan to

end the pandemic." Dr. Rick Bright, *Third Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Dep't of Health and Human Servs*. (Oct. 6, 2020).

56. Concurring with Dr. Bright, experts affirm that an effective pandemic response requires health officials to engage in consistent and coordinated public communication. This involves clear and honest public health guidance, transparent disclosures of government interventions, and timely reporting of the virus' spread. Defendants' withheld duties—commanding public engagement, routine reporting, and pandemic biosurveillance—cut to the heart of effective emergency management. They not only inform the public; they save lives.

57. Regarding the Withheld Biosurveillance Duties, Defendants have, in fact, subverted their own testing, data-collection and public information programs, by, among other things: failing to implement their own comprehensive testing proposals; pushing federal responsibilities enshrined by law onto state and local actors; withdrawing federal funding for testing sites in hotspots experiencing outbreaks; issuing public health guidance contrary to scientific evidence; permitting interference in the routine data-collection and public reporting of Covid-19 case counts; and failing to fulfill promises to provide adequate testing and tracing in order to mitigate the virus' disparate impact along race and ethnicity. As a result, the injuries to Plaintiffs are compounded.

B. Defendants acted arbitrarily, capriciously, and contrary to law when they concealed publicly available Covid-19 transmission data held by the CDC's National Healthcare Safety Network and rerouted case reporting to a closely held, non-public database.

58. On July 15, 2020, the White House ordered all Covid-19 data from local hospitals be routed away from the National Healthcare Safety Network ("NHSN") and to an HHS database that "is not open to the public," "affect[ng] the work of scores of researchers, modelers and health officials who rely on C.D.C. data to make projections and crucial decisions." Sheryl Gay Stolberg,

Trump Administration Strips C.D.C. of Control of Coronavirus Data, N.Y. TIMES (July 14, 2020). NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections." Ctrs. for Disease Control and Prevention, *National Healthcare Safety Network (NHSN)*, CDC.GOV (Sept. 23, 2020).

59. According to Defendants, the same data would now be reported through HHS TeleTracking and made available at HHS Protect. *See* Ctrs. for Disease Control, *CDC Director Dr. Robert R. Redfield and HHS Chief Information Officer Jose Arrieta Remarks on HHS Protect*, CDC.GOV (July 15, 2020).

60. It is not. HHS Protect does not share case numbers or infection rates with the public, but instead shows the percentage of hospitals and other facilities reporting Covid-19 events, a very different measure of the pandemic's progress, and excuses this as a function of the "multiple reporting pathways" the new system must integrate and the fact that hospitals are reporting data that "varies by collection date." Health and Human Servs., *HHS Protect: U.S. Hospital Reporting Dashboard*, HHS.GOV (Oct. 6, 2020).

61. Defendants justified the move from public health surveillance to systems managed by private contractors by claiming that it would streamline reporting and ease the burden on hospitals and health facilities. Defendant Redfield said that "[c]ollecting and disseminating [health] data as rapidly as possible" was "the reason for the policy change." *Id.* He claimed the change "reduces the reporting burden," "reduces confusion and duplication" and "[s]treamlin[ed] reporting." *Id.*

62. It does not. HHS Protect largely does the opposite of what HHS officials said it was intended to do, which has raised serious concerns from public health officials:

(a) According to a letter to Defendant Azar from 22 state attorneys general, "hospitals and state public health departments are incurring substantial costs and operational challenges in trying to respond to the new data requests and reporting system. This sudden disruption threatens to further undermine the nation's already chaotic response to the pandemic." Ltr. from Attorneys Gen. Maura Healey, *et al*., to Health and Human Servs. Sec. Alex Azar (July 28, 2020).

(b) In July 2020, a coalition of stakeholders from the Infectious Diseases Society of America and others identified immediate shortfalls from the change: "Widely accessed Covid-19 tracking sites have already lost access to ICU hospitalization data—a key indicator for monitoring the state of the pandemic." Ltr. from Infectious Diseases Soc'y of Am., *et al*., to V.P. Mike Pence, *et al*. (July 17, 2020).

(c) In August 2020, a month after the switch, data analysis experts at the Covid Tracking Project reported that HHS Protect data was "spotty and difficult to interpret," noting that for several states the HHS data varied widely from the same data reported by state health officials. Rebecca Glassman & Betsy Ladyzhets, *Hospitalization Data Reported by the HHS vs. the States: Jumps, Drops, and Other Unexplained Phenomena*, THE COVID TRACKING PROJECT (Aug. 11, 2020).

(d) In August 2020, former CDC Director Dr. Thomas Frieden noted that the new system was lagging by as much as eleven days and data was being updated only once a week, versus three times per week under NHSN. Robbie Whelan, *Covid-19 Data Reporting System Gets Off to Rocky Start*, WALL ST. J. (Aug. 11, 2020).

63. National Public Radio recently obtained internal HHS emails that show detailed hospital data from the TeleTracking system is provided daily to only a few dozen officials at the CDC and other HHS agencies, including one member of the White House Coronavirus Task Force. *See* Pien Huang *et. al*, *Internal Documents Reveal COVID-19 Hospitalization Data The Government Keeps Hidden*, NPR (Oct. 30, 2020). A smaller subset of that data is made public—usually only once per week—hiding the daily analyses that show sharp increases in hospitalizations and strain on the nation's health system, NPR reported. *Id*. Although HHS says some 800 state public health officials have access to the more detailed data, it is only available for their own state (unless other states agree to share), blinding state officials to regional trends. *Id*.

64. Further, there is no evidence that the government considered the public's reliance interests in the CDC's longstanding NHSN system. Public health officials, researchers, health

systems and hospitals all relied on the NHSN data to make informed decisions about allocation of resources and other aspects of their response to the pandemic.

65. Instead, HHS' stated reasons for the shift were naked pretexts for the creation of a separate, non-public system that HHS and others could manipulate to "play down" the danger and impact of the pandemic. Tellingly, HHS's original directive to hospitals about the change stated that the data submitted to TeleTracking "will greatly assist *the White House Coronavirus Task Force* in tracking the movement of the virus, identifying potential strains in the healthcare system, and informing distribution of supplies." Dep't of Health and Human Servs., Covid-19 Guidance for Hospital Reporting and FAQs, HHS.GOV (July 10, 2020) (emphasis added). After receiving widespread criticism, HHS revised the document to state that the data "will greatly assist *the federal Covid-19 response*," eliding the real reason for the change: putting direct control over data in the hands of the White House Coronavirus Task Force. Dep't of Health and Human Servs., Covid-19 Guidance for Hospital Reporting and FAQs, HHS.GOV (July 29, 2020).

C. Defendants' ongoing failure to perform their statutory obligations and their efforts to undermine federal biosurveillance and data collection have a disproportionate impact on Black and Latinx communities and exacerbate existing health disparities among minorities.

66. Black and Latinx communities have suffered disproportionate negative health risks, infections, personal costs, and loss of life throughout this prolonged pandemic. *See* Richard A. Oppel Jr., *The Fullest Look Yet at the Racial Inequity of Coronavirus*, N.Y. TIMES (July 5, 2020). Federal data—sourced through a Freedom of Information Act request of the CDC—reveals these disparities "span the country, throughout hundreds of counties in urban, suburban and rural areas, and across all age groups." *Id.* Black and Latinx individuals are nearly twice as likely to work in production and service jobs that cannot be performed remotely and similarly more likely to live in crowded housing—amplifying the risks of exposure and transmission. *See id.* As a result, Black

and Latinx persons are approximately three times as likely to become infected and twice as likely to die from Covid-19. *See id*. New York City, where Plaintiffs each reside, experiences firsthand this disparate cast of infections and deaths across race. Matt Stieb, *NYC Department of Health: Black and Latino New Yorkers Dying at 'Around Twice the Rate' of Whites*, N.Y. MAG. (May 18, 2020) (describing the same disparate impact occurring in New York City).

67. In addition to the direct health risks, these disparities have collateral impacts to livelihoods and wellness. People of color are disproportionately likely to lose their jobs or be furloughed without pay. Lena V. Groeger, *What Coronavirus Job Losses Reveal About Racism in America*, PROPUBLICA, July 20, 2020; to become housing insecure, Solomon Greene et al, *New Data Suggest Covid-19 is Widening Housing Disparities by Race and Income*, URBAN INSTITUTE, May 29, 2020; and to suffer mental health strain and illness during the pandemic. SAMHSA, *Double Jeopardy: Covid-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S.*, SAMHSA.GOV (last visited Oct. 21, 2020).

68. HHS has an explicit mandate to study and mitigate the impact of public health risks on "ethnic and racial populations," 42 U.S.C. § 242k(l) and (m), yet the Federal government fails to do so. Moreover, as enumerated above, Defendants fail their duties to plan for and report on research and mitigation strategies with respect to health disparities along race and ethnicity, in violation of not one but at least three separate statutes. *See* 42 U.S.C. § 299a-1(a)(6), 42 U.S.C. § 300u-6(f), and 42 U.S.C. § 285t(d-f).

69. The CDC continues to release data irregularly and in ways that are not easily accessible or digestible. Pursuant to the Paycheck Protection & Health Care Enhancement Act, the CDC was given $1 billion to support its data collection and surveillance efforts, but has failed to properly track the race and ethnicity of Covid-19 patients. Ltr. from Elizabeth Warren, et al., to

Robert Redfield (Apr. 29, 2020). Indeed, Defendant Redfield acknowledged and apologized for the CDC's reporting lapses on Covid-19 disparities, which he described before Congress as "not adequate." *Center for Disease Control Director Testimony on Coronavirus*, C-SPAN (June 4, 2020).

70. On June 9, 2020, Assistant Secretary Giroir, in charge of Covid-19 testing for HHS, conceded while testifying before Congress that the government has not tracked at any length what percentage of people getting tested for the coronavirus are minorities. He called that a "flaw in the system." *Senate Hearing on Procurement and Distribution Strategies in Response to Coronavirus Pandemic*, C-SPAN (June 9, 2020). "We're flying blind until this comes in," Giroir said. *Id.* "We can't develop a national strategy to reach the underserved or know how well we're doing, until we have the data that shows us if we're reaching them or not." *Id.*

71. 52 percent of reported coronavirus cases in the U.S. are still missing information on race or ethnicity—data the government did not begin collecting until August and for which there are still persistent gaps. Data collection disparities among individual states continue unabated and have grown ever wider. Though federal guidelines have been updated to encourage (but not mandate) states and localities to collect such data, the information remains persistently unreported by many and the guidelines do not ask health providers or state and local health departments to backfill any missing data during some of the worst surges of Covid-19 transmission.

72. Experts say that the persistent lack of data could obscure the needs of the most vulnerable communities to get the testing, contact tracing and resources for hospitals and clinics they need as new cases surge. It could also undermine preparedness for a second wave. For example, stakeholder groups including the Infectious Diseases Society of America wrote to Secretary Azar, "Data transparency is particularly critical in the midst of an unprecedented national

health crisis that is disproportionately impacting certain segments of the U.S. population, including Black/African American, Latinx and Native American communities." Ltr. from Infectious Diseases Soc'y of Am., *et al*., to V.P. Mike Pence, *et al*. (July 17, 2020).

73. These shortfalls are especially relevant to the question of school operations and closures during the Covid-19 pandemic, in part because remote learning has a particularly adverse impact on Black and Latinx students. Emily Oster, *Covid-19, Learning Loss and Inequality*, COVID EXPLAINED (June 15, 2020). Minority students disproportionately face financial and logistical challenges related to accessing online learning resources, as well as other risk factors presenting obstacles to sustainable education at home. *See, e.g.*, Benjamin Herold, *The Disparities in Remote Learning Under the Coronavirus (in Charts)*, EDUCATION WEEK (Apr. 10, 2020), and Dana Goldstein, *Research Shows Students Falling Months Behind During Virus Disruptions*, N.Y. TIMES (Jun 10, 2020). Again, the Federal government fails to meet its statutory duties.

D. As we enter the fall/winter, New York City's Covid-19 case rates are rising, threatening the beginning of a second wave of surging infections.

74. New York City has been among the worst impacted cities throughout the pandemic. Though the worst surge of cases appeared in March and April, a large city such as New York routinely reports significant infection numbers, and always carries significant risks of a second large outbreak. The City holds roughly 2.5 percent of the nation's population and to date it has endured roughly 15 percent of the nation's Covid-19 casualties.

75. As cooler weather approaches, and the flu season begins, Covid-19 case numbers both nationally and in New York City have begun to rise threatening a second surge. On October 23, 2020, more than 85,000 new coronavirus cases were reported across the United States, breaking the single-day record set on July 16 by about 10,000 cases. Campbell Robertson *et al*, *U.S. Sets Coronavirus Case Record Amid New Surge*, N.Y. TIMES (Oct. 23, 2020). On October

29, new infections in the United States topped 90,000. Mitch Smith, Simon Romero, and Giulia McDonnell Nieto del Rio, *As Virus Cases Rise Across the U.S., Records Topple*, N.Y. TIMES (Oct. 30, 2020). The University of Washington's Institute for Health Metrics and Evaluation projects Covid-19 could kill roughly 3,500 people a day (and approximately 350,000 dead total) by the end of December. Univ. of Wash., Inst. for Health Metrics and Evaluations, *Covid-19 Projections: Total Deaths and Daily Deaths*, HEALTHDATA.ORG (Oct. 14, 2020).

76. New York City is witnessing a marked return of higher infection rates. Though the city's overall infection rate remains low (averaging 1.5 percent), case rates in nine ZIP codes saw infection rates rise rapidly in recent weeks. These areas included portions of Queens, and Borough Park, Gravesend, Midwood, and Sheepshead Bay in Brooklyn. In reaction, schools and small businesses have been closed. Eleven more ZIP codes saw rapid rises in infection but not to the same degree, including, Bedford-Stuyvesant, Fort Greene, Clinton Hill, Kensington and Crown Heights in Brooklyn; and areas of Queens.

77. These neighborhoods directly implicate Plaintiffs in this case. CIP campuses reside in Gravesend and Sheepshead Bay and serve students in nearby neighborhoods listed above. Housing Works' Brooklyn-based health centers and housing similarly reside in and/or serve patients from these neighborhoods, including Bedford-Stuyvesant, Fort Greene and Clinton Hill. SUNY Downstate Health Sciences University and Medical Center, where Plaintiff Greenberg attends medical school and participates in patient care, is located near Crown Heights and Flatbush and serves patients from neighborhoods like Borough Park, Midwood and Kensington. Washington Heights, in Plaintiff Levine's district and where he resides, was in September the only Manhattan neighborhood to be named among recent hotspots.

78. Plaintiffs anticipate being on the frontlines of any second surge of Covid-19 in New York City, without the benefit of critical reporting that Defendants withhold and lacking the biosurveillance infrastructure that Defendants should have taken numerous steps to create.

E. Plaintiff CIP, Plaintiff Leslie-Bernard Joseph, and CIP's community of students, their families and staff have been irreparably harmed by Defendants' derogation of their duties during this public health emergency.

79. CIP is a free public charter school in Brooklyn, New York, serving more than 1,000 students from kindergarten through twelfth grade across three campuses. Located in the Coney Island, Bath Beach and Gravesend neighborhoods, it is dedicated to preparing every scholar for the college or career of their choice, and to providing its students with opportunities available at the best schools in the city.

80. CIP serves a diverse community of students and families: 43% of scholars identify as Black, 30% Latinx, 16% White, 10% Asian, and 1% Multi-Racial; families speak over two dozen languages and include immigrants from Africa, Asia, Europe, and Latin America; 22% of students have special needs, and for 14% English is not their first language. As an expression of its families' economic need, approximately 86% of CIP scholars are eligible for federal food assistance through the school.

81. CIP's neighborhood and community have been especially hard hit during the pandemic. The virus has disproportionately infected Black and Latinx New Yorkers, immigrants, and essential workers, all of whom are over-represented in CIP's community. As of May, the ZIP code 11224, spanning parts of Coney Island and the Sheepshead Bay, had the second highest death rate in Brooklyn: one in 240 people died. *Brooklyn Area Has N.Y.C.'s Highest Death Rate by ZIP Code*, N.Y. TIMES (May 18, 2020). This fell heavily on CIP families and staff who saw countless infections and suffered more than a dozen dead.

82. CIP families and staff have also disproportionately suffered from the collateral consequences of the pandemic and quarantine. More than 100 CIP parents lost their jobs or were furloughed without pay. The quarantine and shut-down placed additional burdens on single-parent households, exacerbated some families' psychological and other challenges, and threatened others with canceled services or eviction. Households caring for elder family members or those with pre-existing conditions have been especially vulnerable to dangerous outcomes.

83. As a result, CIP and Mr. Joseph diverted resources and took several extraordinary steps necessary to continue to serve its education mission while keeping its community safe, including, but not limited to: closing the school ahead of city and state mandates; building an online learning platform and training faculty; loaning laptops or tablets to ensure every student has a device for remote schooling; providing meals to students and families through CIP facilities, a mobile food truck, and food delivery services; and providing microgrants to more than 125 families so that students can continue their education.

84. Joseph engaged a global consulting firm to study Covid-19 best practices, and based on that research, CIP has taken additional steps this fall, including but not limited to: procuring medical equipment, personal protective equipment ("PPE") and disinfectants; altering facilities to serve smaller classes; and instituting protocols for deep cleaning, mask wearing, physical distancing, restricting shared materials, communicating health updates, and at-home health monitoring. CIP made its blueprint publicly available, and it has been shared as a model for schools across the country.

85. CIP is on the frontlines of the pandemic, protecting and providing for the health of its students and the public health of its community. Schools like CIP are akin to primary health care providers, offering immediate urgent care and coordinating the physical and mental health of

its students as well as other public health duties. In an abundance of caution, CIP has started the new school year remotely until it can establish that it can safely reopen.

86. With respect to Defendants' Withheld Biosurveillance Duties, CIP and its CEO Mr. Joseph are among the categories of persons and entities who are entitled to and would benefit from information transparency into the federal government's health surveillance plans. Given their role serving the health and safety of their students, families and staff, CIP and Mr. Joseph are also among the categories of persons and entities who would benefit from and are eligible to participate in the development and implementation of a federal biosurveillance program. Given the preparations CIP has taken with respect to Covid-19, the federal government will benefit from the lessons of their experience.

87. With respect to Defendants' Withheld Reporting Duties, Defendants fail to disclose information that is essential to CIP's and Mr. Joseph's role serving the public health needs of their community as well as their specific efforts to combat Covid-19. That information is also necessary for CIP and Mr. Joseph to understand the wider public health risks, interpret and evaluate programs of its partners and vendors, learn from the successes and failures in other jurisdictions, plan for adverse eventualities, and manage decisions with respect to staffing, training and procurement protocols. CIP shares its plans with partner organizations and the wider charter school community, so its well-informed conduct can have positive downstream effects.

88. The need for this information is made all the more acute due to the connection between public health and public education. Studies have shown that the costs of the Covid-19 pandemic are falling disproportionately on the educations of Black and Latinx students. Information as to health disparities along race and ethnicity are directly relevant to CIP's mission and other dimensions of their programs. CIP operates in a racially and ethnically diverse part of

Brooklyn, and its students, families and staff experienced disproportionate infections and fatalities due to Covid-19.

89. With respect to Defendants' Withheld Participation Duties, the national debate over reopening schools makes clear that CIP and Mr. Joseph are on the frontlines of the present emergency and that they play an essential role providing for the health of their community. Federal officials have made clear that, like many essential businesses, schools are pressured to open this fall despite the risks involved. CIP and Mr. Joseph serve not just their students, family and staff, but a wider network of leaders in the education sector and in Black and Latinx communities, whose participation have not been sufficiently represented in the federal government's emergency preparations to date. CIP and Mr. Joseph's experience and perspective is directly relevant to regulations and rules in question and the kind of input the government is intended to invite through public participation. Moreover, CIP and its leadership would benefit from the information released in any resulting reports.

90. Accordingly, with respect to Defendant's Withheld Biosurveillance Duties, their Withheld Reporting Duties, and their Withheld Participation Duties, CIP and Mr. Joseph's injuries fall within the zone of interests of the Pandemic Preparedness Act and other public health laws and constitute numerous concrete, particular, and ongoing harms.

F. Plaintiff Housing Works, Plaintiff Charles King and Housing Works' community of patients, residents and staff have been irreparably harmed by Defendants' derogation of their duties during this public health emergency.

91. Housing Works is a community-based, not–for–profit organization dedicated to ending the dual crises of homelessness and AIDS. Since 1990, Housing Works has directly provided more than 30,000 men, women, and children a full range of services, including but not limited to health and mental health care, addiction counseling and treatment, supportive housing,

legal services, job training and advocacy. Approximately 92% of the people participating in Housing Works' services are Black and/or Latinx and face disproportionate likelihood of exposure to and death from Covid-19.

92. Charles King is the CEO and a founder of Housing Works. As a minister, organizer and advocate, he has spent his career in the fight against HIV/AIDS. He served on the governing body of UNAIDS and was Co-Chair of the New York State End of AIDS Task Force. He is currently the Co-Chair of the Ending the Epidemic Subcommittee of the New York State AIDS Advisory Council; of ACT Now: End AIDS; and of the Visioning Committee of the National AIDS Housing Coalition. He holds both a law degree and a master's degree in divinity from Yale. He resides in Manhattan, New York, at a Housing Works facility in Harlem.

93. Housing Works also took proactive steps to partner with the city to play an active role in combating the pandemic.

(a) In April, at the peak of New York City's first outbreak, Housing Works partnered with the City's Department of Social Services to open a shelter in a city hotel to isolate homeless persons discharged from hospitals after testing positive for Covid-19—sheltering approximately 552 people. In July 2020, Housing Works partnered with city agencies to provide health and mental health services in city shelters for the homeless and for formerly incarcerated men granted early release due to high Covid-19 risks in state prisons

(b) In July, at the City's request, Housing Works began to provide Covid-19 testing in City supportive housing facilities, and, in partnership with Health and Hospitals, Housing Works expanded to offer free Covid-19 testing at Housing Works health centers. Since their testing programs began, they have tested nearly 3,000 people.

(c) Additionally, Housing Works has helped to distribute necessary PPE to frontline health workers and others at risk and have distributed over 3 million pieces of PPE including gowns, protective suits, gloves, masks, and face shields, to over 170,000 people including health care workers, homeless service providers, homeless people, patients, and low-income people living in public housing.

94. Housing Works has had to divert resources and take proactive steps to respond to the threats posed by Covid-19 to their clients, patients and staff, including but not limited to:

(a) Providing much of its medical and mental health care remotely, resulting in: decreased participation in online therapy; decreased adherence to medical treatment; irregular pick-ups of meals; and a rise in overdoses;

(b) Instituting in residences strict social distancing, mask and hygiene protocols and restricted socialization programs, group activities and visitors;

(c) Adapting other programs, such as remote legal services and job readiness programs; restrictions to advocacy efforts; closing all retail outlets; expanding online sales and fundraising; and cancelling the annual fundraising events.

95. With respect to Defendants' Withheld Biosurveillance Duties, Housing Works and its CEO Charles King are among the categories of persons and entities who are entitled to and would benefit from the information and transparency that has been denied. As an entity performing Covid-19 testing and contact tracing for its patients and on behalf of the city—as well as leading other healthcare and advocacy programs—Housing Works does not merely stand to benefit from a biosurveillance network; it is a community health organization that would be *actively participating in and reporting data* to such a system. Housing Works and its CEO Charles King are also among the categories of persons and entities eligible to participate in development of the biosurveillance network and its governing rules—through which Housing Works and Mr. King can contribute the lessons of their experience and advocate on behalf of their community of partners, clients and patients.

96. With respect to Defendants' Withheld Reporting Duties, Defendants have denied Housing Works information that is essential to their lifesaving operations and Covid-19 response. Such information shapes their understanding of the wider public health risks, interpret and evaluate programs of partner organizations and other jurisdictions, plan for adverse eventualities, and informs its staffing, training and procurement protocols. Housing Works and Mr. King make routine efforts to keep abreast of the latest public health and government information. Their health staff convenes twice weekly to be briefed on the latest data and protocols, including but not limited

to the latest information on testing, vaccines, transmission, and treatment. Housing Works' best practices spread through their partner organizations, so its well-informed conduct can have positive downstream effects.

97. Indeed, Housing Works—along with several other organizations that include doctors, healthcare professionals, scientists, community workers, activists, and epidemiologists—formed the Covid-19 Working Group-New York ("CWG-NY"), whose members brought the expertise they earned combatting other infectious diseases such as HIV, Hepatitis C, and tuberculosis to propose solutions for Covid-19. CWG-NY's recommendations included overcoming barriers to health care, safe isolation spaces, and income and safety net services, as well as diagnostics and treatment pipelines for Covid-19 for marginalized New Yorkers. Through CWG-NY, Housing Works expressly advocated on behalf of Black and Latinx New Yorkers for whom healthcare equity had long been denied, focusing on gaps in data and transparency with respect to the public health of communities of color that have grown more severe during the pandemic. CWG-NY called for improved data transparency, testing, and contact tracing in order to direct isolation, treatment, and preventative care to communities of color and accurate, transparent data on the public health response in order to monitor and evaluate such efforts.

98. With respect to Defendants' Withheld Participation Duties, Housing Works and Mr. King routinely take advantage of such participatory opportunities (including submitting comments on regulations), and they are among the stakeholders expressly relevant to these participatory opportunities. At a moment when health disparities across race and income are widening due to the pandemic, the federal government has effectively closed the door to the thousands of people Housing Works serves and represents—thousands who are presently suffering from the federal government's neglect.

99. Accordingly, with respect to Defendant's Withheld Biosurveillance Duties, their Withheld Reporting Duties, and their Withheld Participation Duties, Housing Works and Mr. King's injuries fall within the zone of interests of the Pandemic Preparedness Act and other public health laws and constitute numerous concrete, particular, and ongoing harms.

G. Plaintiff Mark Levine has been irreparably harmed by Defendants' derogation of their duties during this public health emergency.

100. Mark Levine is a New York City Council Member, representing the 7th District where he resides in Washington Heights, Manhattan, New York with his family. The 7th District is a diverse community, predominantly Black and Latinx, and Mr. Levine's constituents have experienced disproportionate losses from Covid-19, with fatalities five times the rate of wealthier parts of Manhattan.

101. As Chair of the Health Committee, Mr. Levine has worked extensively on the City's response to the Covid-19 pandemic, helping to lead legislative deliberations and public messaging—especially with respect to best practices and health and safety guidance. Since March, the focus of the Council and Mr. Levine's work has been combatting the pandemic: holding hearings on federal, state and local response capacity, and passing legislation with respect to the City's response to this emergency.

102. Mr. Levine and New York City Council need accurate information in order to make critical decisions over the course of the next year: how to reopen schools, how to reopen restaurants to indoor dining, when and how to encourage white collar workers to return to their offices, and how to support the city's many neighborhoods needing surge capacity. They also need accurate data from other states and their cities. Officials estimate that 20% of new cases in New York City are imported from outside the city, so officials like Mr. Levine need accurate information for travel guidance and quarantine protocols. Moreover, City officials like Mr. Levine need to be able to

judge the effectiveness of policy in other jurisdictions: general public health data can influence Covid-19 prognoses and the effectiveness of public health interventions. Robbed of the standardized and comprehensive data from jurisdictions nationwide—to which they were entitled by statute—Mr. Levine and his colleagues have been denied tools they need to combat this novel and deadly virus.

103. Information regarding health disparities among different races and ethnicities are of special relevance to Mr. Levine's work, as he represents a predominantly non-white district in New York City, one that saw a disproportionately large number of Covid-19 infections and fatalities. Because the federal government continues to fail to take specific steps to mitigate these adverse impacts, the burden instead falls on state and local actors. In his role as Chair of the New York City Council Health Committee, Mr. Levine would directly benefit from any reports containing data as to health disparities and/or recommendations as to how to close those gaps.

104. With respect to Defendants' Withheld Biosurveillance Duties, Mr. Levine has been denied information about and opportunities to participate in the development and design of the nation's crucial biosurveillance infrastructure, where his expertise may be useful and his advocacy on behalf of his constituents necessary.

105. With respect to Defendants' Withheld Reporting Duties, Mr. Levine has been denied certain reports and disclosures with respect to the progression of the pandemic, the government's capacity to respond, and the health vulnerabilities of the public. All of this information is critical to Mr. Levine's work as a Council member and Chair of the Health Committee.

106. With respect to Defendants' Withheld Participation Duties, Defendants have robbed Mr. Levine of opportunities to participate in the regulatory process regarding medical

countermeasures; the role genomic engineering technologies might play in furthering local health security and preparedness; and local health facilities' readiness to respond to public health emergencies. Mr. Levine actively participates in public health convenings within and without New York City, and would take advantage of any opportunities allowed to contribute to federal regulation that would benefit New York City.

107. Accordingly, with respect to Defendant's Withheld Biosurveillance Duties, their Withheld Reporting Duties, and their Withheld Participation Duties, Mr. Levine's injuries fall within the zone of interests of the Pandemic Preparedness Act and other public health laws and constitute numerous concrete, particular, and ongoing harms.

H. Plaintiff Alexandra Greenberg has been irreparably harmed by Defendants' derogation of their duties during this public health emergency.

108. Plaintiff Alexandra Greenberg is a second-year medical student at the State University of New York Downstate Health Sciences University ("SUNY Downstate"), and a native New Yorker living on the Upper East Side of Manhattan.

109. After graduating from Stuyvesant High School, she earned a bachelor's degree in public health studies and pre-medicine from Johns Hopkins University, a master's degree in international health from the Johns Hopkins Bloomberg School of Public Health, and a master's degree in Medical Sciences from the Boston University School of Medicine.

110. Ms. Greenberg's public health research has focused on social and behavioral interventions to improve public health, combat infectious diseases, and guarantee access to medicines. She has, among other things, assisted in modeling vaccine distribution, investigated the disease-causing mechanisms of the Ebola virus, and studied inequities in health care among low-income and minority populations. Her work on vaccination campaigns demonstrated that a lack of

transparent and trustworthy information will make it much more difficult to achieve widespread acceptance of any vaccine, including a future Covid-19 vaccine.

111. Ms. Greenberg has also been an active advocate for public health policy reform. Since 2013, she has worked with Universities Allied for Essential Medicines ("UAEM"), a student-led, international nonprofit working to improve access to and affordability of medicines, and as an officer for the organization, she coordinated advocacy campaigns across North America. She also co-founded Right to Health Action, an advocacy organization that works to alleviate the disparities in health and health care that are caused by racial injustice and economic inequality, specifically addressing such disparate outcomes from Covid-19 and future pandemics. On their behalf, she plans online educational and advocacy events, develops policy proposals, and contacts lawmakers. She also works with other SUNY Downstate students in the group to advocate for reform at the school and to address structural disparities arising from the inherent racism in the current medical system.

112. University Hospital of Brooklyn, the hospital affiliated with SUNY Downstate was the sole Covid-only hospital in New York City during the peak of the outbreak this spring. It was well understood that care at all hospitals in New York City, but especially this public hospital specifically chosen to bear the brunt of COVID-19 at its peak, suffered because of lack of state and federal support to address severe shortages of items such as PPE. At SUNY Downstate, as across many hospitals and medical schools in New York, staff and students, like Ms. Greenberg, helped sourcing PPE, and institutions were put in the impossible position of reusing masks and other PPE or substituting items like garbage bags for gowns because of dwindling supplies.

113. At SUNY Downstate, Ms. Greenberg is a member of the Medical Student Council, and the lack of detailed, reliable and timely information about the course of the pandemic has made

it difficult for the council to determine and advocate for the best policies regarding remote instruction, as well as to participate in prevention and mitigation strategies that would have stemmed the rate of transmission or prepared appropriately for strain on medical resources

114. The Covid-19 pandemic has severely disrupted Ms. Greenberg's medical education: in-person have been cancelled since March, 2020; since then her education has been administered fully remotely; she has lacking substitutes for hands-on training and clinical work; and aspects of her medical training have been delayed and may be curtailed or forgone altogether.

115. Ms. Greenberg has been irreparably harmed by Defendants' failure to provide their Withheld Biosurveillance Duties, their Withheld Reporting Duties, and their Withheld Participation Duties. Pursuant to her activism combatting disparities in health care and her leadership in her medical student body, she would benefit from the information Defendants have withheld, and she is well-positioned to provide solid, scientifically valid comments to federal agencies and members of Congress as they develop policies and practices for combatting the Covid-19 pandemic. Ms. Greenberg regularly participates in public health convenings around the world and engages actively in public health and policy advocacy. She would take advantage of any opportunities afforded her by law to participate in making public health policy. The federal government's failure to seek or even allow for such public comments has harmed her ability to advocate for policies that could not only save lives but also improve the just and fair operation of our healthcare system.

116. Accordingly, with respect to Defendant's Withheld Biosurveillance Duties, their Withheld Reporting Duties, and their Withheld Participation Duties, Ms. Greenberg's injuries fall within the zone of interests of the Pandemic Preparedness Act and other public health laws and constitute numerous concrete, particular, and ongoing harms.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violations of the Administrative Procedure Act
5 U.S.C. § 706(1) and § 706(2)(D)

117. Plaintiffs repeat, realleges, and incorporate by reference all of the allegations contained in the preceding paragraphs as if fully set forth herein.

118. The APA empowers courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

119. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

120. HHS and CDC are each an "agency" within the meaning of the APA. 5 U.S.C. § 551(1).

121. Defendants Azar and Redfield have violated their duties under the Pandemic Preparedness Act, including those codified at 42 U.S.C. § 247d-4, with respect to public health surveillance and biosurveillance networks, specifically: (1) to convene a public meeting "for purposes of discussing and providing input on the potential goals, functions, and uses of the network" and to include representatives from federal, state, local and tribal health agencies, public and private sector expertise, and other such stakeholders, 42 U.S.C. § 247d-4(c)(5)(B); (2) to submit to Congress and publish the Biological Threat Detection Report on "the capabilities of detection systems in use by Federal departments and agencies," including their ability to support corresponding state and local efforts, P.L. 116-22 § 205(c), 133 Stat. 905, 924–25; and (3) to develop, promulgate, and publish online the "technical and reporting standards, including standards for interoperability" of federal, state, local, tribal, and private organizations, 42 U.S.C. § 247d-4(b)(2)-(3). Alongside these failed duties, Defendants Azar and Redfield have also denied

Plaintiffs the formal notice and opportunity to provide comment, pursuant to 5 U.S.C. § 533, with respect to the standards he was obligated to promulgate under 42 U.S.C. § 247d-4(b)(3).

122. Absent fulfilling these mandatory prerequisites, Defendant Azar cannot fulfill his contingent duties under 42 U.S.C. § 247d-4(c) to develop a biosurveillance network for "near real time" reporting to the public on public health emergencies such as the ongoing Covid-19 pandemic, or submit his required Biosurveillance SIP, 42 U.S.C. § 247d-4(c)(6), to Congress.

123. Defendants Azar and Kadlec have also violated a number of additional duties implementing public disclosure and transparency. In doing so, they have violated HHS's express charge to "coordinate . . . all health statistical and epidemiological activities," 42 U.S.C. § 242b(c)(1), to gather "high quality, timely, and comprehensive" public health information, 42 U.S.C. § 242m(c), and to distribute it on "as wide a basis as possible," *id.* Defendants Azar and Kadlec have also violated the legislative purpose of the Pandemic Preparedness Act, as well as the statutory scheme of certain United States' public health laws, to improve transparency, oversight and public participation in the development and execution of our public health system. *See* P.L. 116-22, 133 Stat. 905. Defendants Azar and Kadlec have also violated the custom and past practice of the HHS upon which Platinfffs and the public rely. These general duties permeate each of Defendants' failed disclosures.

124. Defendants Azar and Kadlec have violated a number of express statutory duties to prepare certain reports that must be made publicly available:

(a) Secretary Azar's duties, under 42 U.S.C. § 247d-3a and *id.* § 247d-3b, as amended by the Pandemic Preparedness Act, to prepare and "publish . . . on a Federal Internet website", *id.* § 247d-3a(i)(1)(E), annual reports submitted to the agency from state and local entities receiving related federal funding, *id.* § 247d-3a(i)(1), *id.* § 247d-3b(i)(1), and to "also compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website," *id.* § 247d-3a(j);

(b) Assistant Secretary Kadlec's duties, under 42 U.S.C. § 300hh-10(d) as amended by the Pandemic Preparedness Act, no later than March 15, 2020 to prepare a

Countermeasures SIP, *id.* § 300hh-10(d)(1), that is "require[d]" to be "made publicly available," *id.* § 300hh-10(d)(2), (2)(K); and;

(c) Assistant Secretary Kadlec's duties under 42 U.S.C. § 300hh-10(b)(7) no later than March 15, 2020 to "[d]evelop and update" a five-year budget plan based on the priorities in the Countermeasures SIP, 42 U.S.C. § 300hh-10(b)(7), and "ma[k]e [it] publicly available on the same date, *id.* § 300hh-10(b)(7)(F).

125. Defendant Azar has violated a number of express statutory duties to prepare certain reports for which an additional statutory provision requires them to be made publicly available:

(a) Secretary Azar's duties, under 42 U.S.C. § 242m(a), no later than March 15 each year to prepare and submit to Congress and the President four annual reports, *id.* § 242m(a)(1), on the nation's "health," "health care," "health resources," and their use, *id.* § 242m(a)(1)(A-D), which rely on statistics collected pursuant to 42 U.S.C. § 242(k)(b)(1), and must be "published" and "ma[d]e available" under 42 U.S.C. § 242m(c);

(b) Secretary Azar's duties, under 42 U.S.C. § 242p, to prepare and submit to Congress on March 15, 2020 a national disease prevention data profile, *id.* § 242p(a), specifically to include certain data such as on "mortality and morbidity," *id.* § 242p(a)(1-4), for the express purpose of "increas[ing] public awareness of the prevalence, incidence, and any trends in the preventable causes of death and disability in the United States," *id.* § 242p(a), and must comply with additional provisions for public disclosure, *id.* § 242p(b) (citing *id.* § 242m); and;

(c) Secretary Azar's duties, under 42 U.S.C. § 247d-6b(c), to submit to Congress "on an annual basis all current material threat determinations," 42 U.S.C. § 247d-6b(c)(2)(C), and to "institute a process for making publicly available the results of [such] assessments" of material threats and the sufficiency of SNS countermeasures, *see* 42 U.S.C. § 247d-6b(c)(3)(A-B).

126. Defendant Azar has violated a number of express statutory duties to prepare certain reports and, consistent with custom and past practice, to make them publicly available:

(a) Secretary Azar's duties, under 42 U.S.C. § 262a(k)(2)(A), by June 24, 2020 to submit to Congress a report on the implementation of the FESAP recommendations regarding biological agents, toxins and their countermeasures, which have been published in some form since 2010;

(b) Secretary Azar's duties under 42 U.S.C. § 299a-1(a)(6) to prepare and submit to Congress an annual National Healthcare Quality and Disparities Report, published online since 2003 until 2018;

(c) Secretary Azar, duties under 42 U.S.C. § 300u-6(f)(1), no later than February 1, 2019 and biennially thereafter to prepare and submit to Congress a report from the OMH

on the office's activities and "the extent to which such activities have been effective in improving the health of racial and ethnic minority groups," versions of which were provided online until 2015; and;

127. Defendant Azar has violated a number of express statutory duties to prepare certain reports and, consistent with the statutory scheme taken as a whole, to make them publicly available:

(a) Secretary Azar's duties, under 42 U.S.C. § 247d-6b(a)(2), to prepare and submit to Congress before March 15, 2020, *id.* § 247d-6b(a)(2)(A), an annual Threat-Based Review with respect to the sufficiency of SNS countermeasures for combatting public health threats, *id*. (citing 42 U.S.C. § 300hh-10), and regarding information intended for the public under *id.* § 300hh-10 and *id.* § 247d-6b(c)(3)(A-B);

(b) Secretary Azar's duties under P.L. 116-22 § 606, 133 Stat. 905, 959 to prepare and submit to Congress, by June 24, 2020, a report on international coordination "during recent public health emergencies with respect to the research and advanced research on, and development of, qualified pandemic or epidemic countermeasures," including "vaccine[s]," *id.*, including guidance on what information may and may not be included so as to not "compromise national security," indicating it is intended to be made public, *id.*; and;

(c) Secretary Azar' s duties under the Pandemic Preparedness Act, P.L. 116-22 § 209, 133 Stat. 905, 929, to prepare and submit to Congress, before June 24, 2020, a report containing recommendations related to maintaining an adequate national blood supply, *id.*.

128. Defendants Azar and Kadlec have also violated a number of additional duties related to public participation under the Pandemic Preparedness Act and other statutes, despite the fact that the PPA extensively calls for public input and expertise and demonstrates Congress's intent to involve the public in HHS's duties:

(a) Secretary Azar's duties, under P.L. 116-22 § 605, 133 Stat. 905, 958-59, not later than June 24, 2020, to convene a meeting to discuss genomic engineering technologies, health security, and potential medical countermeasures, to include "representatives from academic, private, and nonprofit entities . . . and other stakeholders," after which Defendants must prepare a report; and;

(b) Assistant Secretary Kadlec's duties, under 42 U.S.C. § 300hh-10(d)(2)(H), with respect to, to solicit input from relevant state, local, tribal and territorial stakeholders prior to its creation and incorporate it into the Countermeasures SIP.

129. Defendants have failed to satisfy their above-enumerated duties (*infra* pp. 121-128) for multiple years, and as a result have withheld multiple iterations of various reports and disclosures.

130. Defendants have failed to satisfy additional statutory duties to provide notice and/or opportunity for comment, information, and participation to the Congress and/or the public.

131. Accordingly, Plaintiffs have been injured in that they have been denied vital information with respect to the Covid-19 pandemic—its spread and prevalence in the community, the comprehensiveness of the data collected and made available, and the nation's capacity and efforts to respond effectively—that is critical to their ability to conduct themselves safely and to protect their members and communities from adverse outcomes during this public health crisis.

132. Plaintiffs have also been injured in that they have been denied procedural opportunities to participate in and give notice and comment on vital aspects of the government's pandemic preparations and response capacity. Absent such opportunities, Plaintiffs—all of whom play vital roles in the health and safety of their communities—have lost the opportunity to contribute their needs and knowledge to the regulatory process.

133. Such injuries have also forced Plaintiffs to divert resources that they would have dedicated otherwise.

134. Defendants' violations under 42 U.S.C. § 242b; 42 U.S.C. § 242m; 42 U.S.C. § 242p; 42 U.S.C. § 247d-3a; 42 U.S.C. § 247d-3b; 42 U.S.C. § 247d-4; 42 U.S.C. § 247d-6b; 42 U.S.C. § 262a; 42 U.S.C. § 299a-1; 42 U.S.C. § 300hh-10; 42 U.S.C. § 300u-6; P.L. 116-22 § 205, 133 Stat. 905, 924–25; P.L. 116-22 § 209, 133 Stat. 905, 929; P.L. 116-22 § 605, 133 Stat. 905, 958-59, and P.L. 116-22 § 606, 133 Stat. 905, 959 constitute discrete agency actions "unlawfully withheld or unreasonably delayed" within the meaning of the APA, 5 U.S.C. § 706(1).

135. Defendants' violations under 42 U.S.C. § 242b; 42 U.S.C. § 242m; 42 U.S.C. § 242p; 42 U.S.C. § 247d-3a; 42 U.S.C. § 247d-3b; 42 U.S.C. § 247d-4; 42 U.S.C. § 247d-6b; 42 U.S.C. § 262a; 42 U.S.C. § 299a-1; 42 U.S.C. § 300hh-10; 42 U.S.C. § 300u-6; P.L. 116-22 § 205, 133 Stat. 905, 924–25; P.L. 116-22 § 209, 133 Stat. 905, 929; P.L. 116-22 § 605, 133 Stat. 905, 958-59, and P.L. 116-22 § 606, 133 Stat. 905, 959 constitute discrete agency actions "without observance of procedure required by law" within the meaning of the APA, 5 U.S.C. § 706(2)(D).

136. Accordingly, Plaintiffs seek a declaration pursuant to 28 U.S.C. § 2201 that Defendants have unlawfully withheld or unreasonably delayed performance of statutory duties to data collection, public participation, and reporting, described above, in violation of 5 U.S.C. § 706(1) and that Defendants fail to observe procedure required by law, in violation of 5 U.S.C. § 706(2)(D). Plaintiffs seek a preliminary and permanent injunction pursuant to 5 U.S.C. §§ 706(1) and 706(2)(D) compelling performance of those obligations and sufficient public health surveillance to meet their statutory mandates and future reporting obligations, including their duties to study and mitigate public health risks to racial and ethnic populations from Covid-19. Plaintiffs seek orders compelling prompt relief according to a schedule set by the Court. Plaintiffs also seek an order for the Court to retain jurisdiction and place such relief under court supervision or receivership to ensure Defendants' performance of court ordered relief.

SECOND CLAIM FOR RELIEF
Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) and (C) and Violation of the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq.*

137. Plaintiffs repeat, reallege, and incorporate by reference all of the allegations contained in the preceding paragraphs as if fully set forth herein.

138. The APA prohibits federal agency action that is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law" and "in excess of statutory jurisdiction, authority or limitations, or short of a statutory right." 5 U.S.C. § 706(2)(A) and (C).

139. Defendants have taken action that has had a deleterious effect on their capacity to respond to Covid-19, to collect adequate data on its transmission and spread, and to report such information publicly and transparently, in violation of 5 U.S.C § 706(2)(A) and (C).

140. Defendants ordered all data from local hospitals be routed away from the NHSN, a publicly available CDC database, and directly to a privately managed HHS Protect database, denying public access to such information and adding further difficulty to state and local officials, health researchers, and the wider public who rely on transparent data and disclosures.

141. The above-mentioned action is contrary to the scientific evidence before the agency; the agency failed to consider the impact of incomplete data in the public's ability to combat a novel public health threat; the agency failed to justify the ways the decision departs from present guidelines, standards and practices; and the decision is a pretext for wrongfully narrowing data collection and reporting on behalf of the President's political and personal interests.

142. Defendants' action is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law, violates statutory obligations for public disclosure of federal health data, and therefore violated the APA, 5 U.S.C. § 706(2)(A) and (C).

143. Defendants' action constitutes a rulemaking, and they have denied Plaintiffs the formal notice and opportunity to provide comment to which they are entitled, pursuant to 5 U.S.C. § 533,

144. HHS failed to conduct any regulatory flexibility analysis to determine how rerouting Covid-19 case reporting from public CDC databases to non-public databases would impact small entities, such as Plaintiffs CIP and Housing Works, in violation of the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq* ("RFA").

145. Plaintiffs CIP and Housing Works are "small organizations" within the meaning of 5 U.S.C. §§ 601(4) and are directly affected by the rerouting of Covid-19 case data, insofar as they depend on timely and transparent reporting in order to conduct their operations safely and effectively, and therefore Defendants were required to conduct a regulatory flexibility analysis prior to promulgating the rule.

146. It is undisputed that Defendants failed to conduct a regulatory flexibility analysis.

147. Defendants action violated the RFA, 5 U.S.C. §§ 601 *et seq*.

148. Accordingly, Plaintiffs seek a declaration pursuant to 28 U.S.C. § 2201 that the above-described action with respect to Covid-19 data collection and reporting are substantively and procedurally unlawful under the Administrative Procedures Act and violate the Regulatory Flexibility Act. Plaintiffs seek a preliminary and permanent injunction reversing the above action, restoring regularly reported Covid-19 data to near real-time publicly accessible databases, and reinstating the NHSN's Covid-19 data collection programs. Plaintiffs also seek an injunction requiring Defendants to perform regulatory flexibility analyses with respect to all future rulemaking related to Covid-19 data collection. Plaintiffs also seek an order for the Court to retain jurisdiction and place such relief under court supervision or receivership to ensure Defendants' performance of court-ordered relief.

THIRD CLAIM FOR RELIEF
Writs Pursuant to the Mandamus Act, 28 U.S.C. § 1361 and the All Writs Act, 28 U.S.C. § 1651(a)

149. Plaintiffs repeat, reallege, and incorporate by reference all of the allegations contained in the preceding paragraphs as if fully set forth herein.

150. The All Writs Act empowers courts to "issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law," 28 U.S.C.

§ 1651(a), and the Mandamus Act empowers courts to "compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff," 28 U.S.C. § 1361.

151. HHS and CDC are each an "agency" within the meaning of the Mandamus Act, and Defendants are officers and employees thereof.

152. As enumerated in detail in the First and Second Claims for Relief, Defendants have violated their duties under numerous public health laws to: 1) develop and implement a federal biosurveillance network for use during public health emergencies; 2) provide reports and other disclosures to the public relevant to public health concerns raised by the Covid-19 pandemic, including reports expressly mandated to be made public by statute, reports for which related statutory language requires disclosure, reports that have made available to the public according to custom and past practice, and reports that ought to be made public under the totality of the statutory scheme and HHS's general duty to provide the public with "high quality, timely, and comprehensive" information; 3) fulfill statutorily mandated opportunities for the public to participate in the regulatory and rulemaking process with respect to public health emergency preparedness and response—and specifically to Covid-19; and 4) have withdrawn regularly reported Covid-19 case data from public access.

153. Plaintiffs have been irreparably injured in that they have been denied vital information with respect to the Covid-19 pandemic and the nation's public health, information critical to their ability to conduct themselves safely and to protect their members and communities effectively and efficiently. Plaintiffs have also been irreparably injured in that they have been denied procedural opportunities to participate in and give notice and comment on vital aspects of the government's pandemic preparations and response capacity. Such injuries have also forced Plaintiffs to divert resources that they would have dedicated otherwise.

154. Defendants' failures of duty and wrongful actions threaten Defendants' ability to fulfill future obligations of a similar nature. The statutorily mandated biosurveillance—and the near real-time information it is intended to provide to the public—will not be manifested absent Defendants' prerequisite duties being met. Similarly, future reports and disclosures will be impossible if past reports, and the underlying data collection have been neglected or altogether unperformed.

155. Given Defendants' wanton pattern of derogation of duty, Plaintiffs injuries will likely repeat into the future and evade review, absent the Court retaining jurisdiction or otherwise supervising Defendants' compliance with their data collection, transparency and oversight duties.

156. With respect to the court's Mandamus Act authority pursuant to 28 U.S.C. § 1361, Plaintiffs have a clear right to the relief sought, a plainly defined and peremptory duty on the part of Defendants to do the act in question, and no other adequate remedy available other than the prospective relief this court may grant.

157. With respect to the Court's All Writs Act authority, pursuant to 28 U.S.C. § 1651(a), Plaintiffs have a clear and indisputable right to the relief sought, they have no other adequate means to attain the relief desired and a writ is appropriate under the circumstances.

158. Accordingly, Plaintiffs seek a declaration pursuant to 28 U.S.C. § 2201 that Defendants have unlawfully withheld or unreasonably delayed performance of statutory duties and Defendants have acted arbitrarily, capriciously, abused their discretion, and otherwise contradicted the law. Plaintiffs seek a preliminary and permanent injunction, under 28 U.S.C. § 1651(a) and 28 U.S.C. § 1361, compelling 1) performance of those obligations, 2) the restoration of regularly reported Covid-19 data to near real-time publicly accessible databases and reinstatement of the NHSN's Covid-19 data collection programs, and 3) the performance of sufficient public health

surveillance to meet their statutory mandates and future reporting obligations, including their duties to study and mitigate public health risks to racial and ethnic populations experiencing disparate health outcomes from Covid-19. Plaintiffs seek orders compelling prompt relief according to a schedule set by the Court. Plaintiffs also seek an order for the Court to retain jurisdiction and place such relief under court supervision or receivership to ensure Defendants' performance of court ordered relief.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray that the Court:

1. Declare that Defendants have unlawfully withheld, or unreasonably delayed actions required to fulfill the above-described duties under the Pandemic Preparedness Act and Public Health Services Act pursuant to the Sections 706(1) and 706(2)(D) of the Administrative Procedure Act, and that Defendants are in violation of said acts;

2. Declare that the above-described action that Defendants took with respect to Covid-19 data collection and reporting is substantively and procedurally unlawful under Sections 706(2)(A) and (C) of the Administrative Procedure Act;

3. Order an injunction compelling Defendants to fulfill the above-described duties under the Pandemic Preparedness Act, Public Health Services Act and other statutes governing the Department of Health and Human Services and remedy every instance that these have been unlawfully withheld or unreasonably delayed since at least January 20, 2017;

4. Order an injunction compelling Defendants to carry out sufficient public health surveillance to ensure they have the data necessary to meet their statutory mandates and future reporting obligations, including their duties to study and mitigate public health risks to racial and ethnic populations experiencing disparate health outcomes from Covid-19;

5. Order an injunction compelling Defendants to reverse the migration of Covid-19 data reporting to HHS Protect, reinstate the NHSN Covid-19 data collection programs, and make all such information publicly available in near real-time;

6. Order an injunction compelling Defendants to perform regulatory flexibility analyses with respect to all future rulemaking related to Covid-19 data collection;

7. Order the above relief according to a schedule set by the Court;

8. Retain jurisdiction over this action and order court supervision or a receivership to ensure compliance with the Court's decree;

9. Award Plaintiffs their costs of litigation, including reasonable attorney's fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412;

10. Grant such other relief as the Court deems just and proper.

Dated: October 30, 2020

Respectfully submitted,

/s/ Norman Siegel

Norman Siegel
Herbert Teitelbaum
Cary McClelland*
Goutam Jois
SIEGEL TEITELBAUM & EVANS, LLP
260 Madison Avenue, 22nd Floor
New York, New York 10016
Phone: (212) 455-0300

**Pro Hac Vice to be filed*

/s/ Kahlil C. Williams

Marjorie J. Peerce
BALLARD SPAHR LLP
1675 Broadway, 19th Floor
New York NY 10019
Phone: (646) 346-8039

Kahlil C. Williams
Michael R. McDonald
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia PA 19103
Phone: (215) 665-5000

CERTIFICATE OF SERVICE

I, Kahlil C. Williams hereby certify that I served the foregoing, with prior consent, on the Office of the United States Attorney for the Southern District of New York.

Dated: October 30, 2020

/s/ Kahlil C. Williams